

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Claims 32-61 in the reply filed on 3/31/2010 is acknowledged.

### ***Claim Objections***

2. Claims 35- 40 and 50-55 are objected to because of the following informalities: Claims 35-40 and 50-55 include, "to any of claims" which is unclear. Examiner suggests deletion of this claim language since the claims only depend upon on claim 32 and not any other claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 42, 47, 57, 59, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 42 and 57 vague and indefinite. Specifically it is unclear if the current is 5% of the stimulation current or if the current is less than 5%, since claim 41, which claim 42 depends, contains the limitation that the current is less than a predetermined fraction of the stimulation current since applicant appears to only have support within the specification for the discharge current being equal to a preset fraction, and the preset fraction being equal to 5%, not less than.

6. Claims 45, 47, 59, and 61 are vague and indefinite. Specifically the "targeted voltage" that is incremented or decremented in response to the measured second electrode potential, lacks structural and functional connection to the rest of the claimed invention. In other words it is unclear if the targeted voltage is the tissue capacitative voltage or the potential applied to the tissue, or some other voltage.

7. Additionally, it is unclear what applicant considers a true signal and a false signal.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 32-37, 40, 43, 46, 48-53, 55, and 60, are rejected under 35 U.S.C. 102(b) as being anticipated by Najafi et al. (US 5,314,458).

10. Najafi discloses a system and method for stimulating patient tissue comprising a microstimulator that applies a voltage to the tissue (e.g. ABSTRACT). Examiner considers patient tissue to necessarily have a capacitance property and therefore voltage will develop across the stimulated tissue, since patient tissue has substantially the same properties in all patients. Najafi discloses discharge circuitry configured to inject a current into the tissue to discharge the capacitative voltage developed. Najafi discloses this feature as charge balancing (e.g. Col. 7, line 51-Col. 8, line 16).

11. With regard to claim 33, Najafi discloses an inductor, e.g. element 14, that supplies energy to the charge capacitor (e.g. ABSTRACT), and a microcontroller (e.g. control logic 31), for regulating duty cycles to charge the capacitor from the inductor.
12. With regard to claim 34, Najafi discloses the charge balance current is a constant current (e.g. Col. 7, line 51- Col. 8, line 16).
13. With regard to claim 36-37, Najafi discloses the injected current will continue until the tissue is charge balanced, which necessarily discloses that the system must sense what the tissue voltage is in order to declare and determine when it has been balanced (e.g. Col. 8, line 3-4).
14. With regard to claim 38, Najafi discloses the control circuitry to supply a command to stop stimulation/applying the potential which defines a stimulation period time (e.g. Col. 7, line 65-67).
15. With regard to claim 40, Examiner considers the charge balance current to eliminate break excitation, since the charge is balanced and there is no resultant charge to create a break excitation.
16. With regard to claim 43, Najafi discloses a battery (e.g. Col. 11, line 35-38), and at least two electrodes (e.g. electrodes 18 and 19 seen in Fig. 3).
17. With regard to claim 46, Najafi discloses the charge circuitry to communicate with the microcontroller and receives commands from the microcontroller to charge and apply the potential, stop applying the potential etc. (e.g. Col. 7, line 51-Col 8, line 16).
18. With regard to claims 35 and 50, Examiner considers any current applied for active discharge to necessarily have a relation to the stimulation current which is

considered a fraction, for instance if the discharge current were equal to the stimulation current the fraction would be 1/1.

***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 41-42, and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Najafi as applied above.

22. Najafi discloses the invention as claimed but fails to explicitly teach the discharge current being a preset fraction, 5%, of the stimulation current. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Najafi with the charge balance current being a fraction less than the stimulation current such as 5%, since it has been held that where the

general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233 and since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215.

23. Claims 38-39, 44, 45, 47, 52, 54, 58, 59, and 61 rejected under 35 U.S.C. 103(a) as being unpatentable over Najafi as applied above in view of Kuehn (US 5,201,865).

24. Najafi discloses the invention as claimed except fails to teach measuring the tissue impedance, detecting the potential on a second electrode, setting a voltage based on the tissue impedance and measured voltage from the second electrode.

25. Keuhn teaches a tissue stimulating system that measures the tissue impedance from a second electrode for a determined time and adjusting (increment or decrement) the pacing energy (targeted voltage) based on the measured impedance values as set forth in Col. 5, line 15-60; Col. 8, line 16-54 for providing the predictable results of ensuring the proper stimulation levels are provided at safe levels and providing power saving management of the implantable device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Najafi with measures the tissue impedance from a second electrode for a determined time and adjusting the pacing energy (targeted voltage) based on the measured impedance values.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joseph Stoklosa  
Examiner  
Art Unit 3762

/Joseph Stoklosa/  
Examiner, Art Unit 3762  
1/20/2011

/Niketa I. Patel/  
Supervisory Patent Examiner, Art Unit 3762